Departments Release FAQs on Over-the-Counter COVID-19 Tests and Other Preventive Services

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The US Departments of Labor, Health and Human Services, and the Treasury (collectively, the Departments) on January 10 published much-anticipated FAQs implementing President Joseph Biden's announcement last month to expand free at-home COVID-19 testing for all Americans during the continued period of public health emergency.

The FAQs expand on existing guidance under the Families First Coronavirus Response Act (FFCRA) and the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) requiring group health plans (including grandfathered plans) to provide certain COVID-19 testing benefits without cost-sharing (deductibles, copayments, and coinsurance), prior authorization, and other medical management requirements during the public health emergency. The CARES Act expanded the FFCRA requirements by requiring group health plans to reimburse certain providers for COVID-19 diagnostic testing. Specifically, FAQs Part 43 (published in June 2020) included guidance on coverage for at-home testing when ordered by an attending health care provider, although at that time the Food and Drug Administration (FDA) had not yet authorized such tests.

Now that the FDA has authorized over-the-counter at-home COVID-19 tests (OTC COVID-19 tests), the FAQs clarify that group health plans must cover such FDA-authorized, cleared, or approved OTC COVID-19 tests for diagnostic purposes, with or without the involvement of a health care provider, effective January 15, 2022 through the end of the public health emergency. The public health emergency is ongoing, and it is unclear when the Department of Health and Human Services will announce its end or let the period expire. This means that group health plans will have to cover the cost of OTC COVID-19 tests at no cost-sharing for an indefinite period, resulting in a significant financial burden for self-insured employers and issuers of group health plan coverage.

In addition to the OTC COVID-19 testing guidance, the Departments also address some preventive care services in the FAQs. Below is a summary of some key points from the FAQs.

Coverage for OTC COVID-19 Tests

Reimbursement for and Access to OTC COVID-19 Tests

- A group health plan must cover the costs of OTC COVID-19 tests for participants either directly (referred to in the FAQs as "direct coverage") or by requiring participants to pay for the tests upfront and then submit a claim for reimbursement. However, the Departments strongly encourage group health plans to provide OTC COVID-19 tests through direct coverage and has provided an incentive for plans to do so.
- If the group health plan provides direct coverage of OTC COVID-19 tests both through its pharmacy network and a direct-to-consumer shipping program, it may limit reimbursement for OTC COVID-19 tests from nonpreferred pharmacies or other retailers to the lesser of $12 per test or the actual cost of the test. This highlights the Departments' clear preference for direct coverage and intent to protect consumers from paying out of pocket for OTC COVID-19 tests. To use this safe harbor, the group health plan must ensure that

participants have access to OTC COVID-19 tests through an adequate number of retail locations (including both in-person and online locations). Adequate access is a facts-and-circumstances determination and depends on the locality of participants under the plan or coverage and current utilization of the group health plan's pharmacy network by its participants. Group health plans should ensure that participants are aware of key information needed to access OTC COVID-19 testing, such as dates of availability of the direct coverage program and participating retailers or other locations, in order to facilitate consumer access and provide for a seamless experience in obtaining free OTC COVID-19 tests.

Limitations on Coverage for OTC COVID-19 Tests

- A group health plan may (but is not required to) limit the number of OTC COVID-19 tests covered for each participant to no less than eight tests per 30-day period (or calendar month). This limit applies to each individual test, even if multiple tests are sold in each box. This limit applies only to tests purchased without a health care provider order or clinical assessment. There is no limit on the number of COVID-19 tests, including OTC COVID-19 tests, a plan must cover if a health care provider orders the test or administers it following a clinical assessment.

Addressing Fraud and Abuse

- A group health plan may take reasonable steps—such as requiring a written attestation—to ensure that each OTC COVID-19 test for which a participant seeks coverage under the group health plan was purchased for personal use, not for employment purposes; has not been (and will not be) reimbursed by another source; and is not for resale. To be reasonable, such steps must not create significant barriers for obtaining the tests.
- A group health plan may require reasonable documentation of proof of purchase with a claim for reimbursement for the cost of an OTC COVID-19 test. This could include documentation of the UPC code for the OTC COVID-19 test and/or a receipt from the seller of the test.
- A group health plan may provide education and information resources meant to support participants seeking and using OTC COVID-19 tests if such resources make clear that the group health plan covers OTC COVID-19 tests. This can include information about how to obtain tests, how to obtain reimbursement for out-of-pocket costs related to testing, explanations of the differences between OTC COVID-19 tests and tests processed in a laboratory, and details related to the reliability of various tests such as shelf life and expiration dates.

Implementing direct coverage for OTC COVID-19 tests is a significant administrative undertaking. With the implementation date of January 15 and the lack of availability of OTC COVID-19 tests, most group health plans will likely not be in the position to provide direct coverage by January 15, cutting off the group health plan's ability to limit reimbursements for testing kits purchased from nonpreferred pharmacies and retailers. Notably missing from the guidance is what recourse, if any, group health plans have against price gouging while gearing up to provide direct coverage. Given the current scarcity of OTC COVID-19 tests, if a participant purchases the only OTC COVID-19 test that they can find for $100 (even though that test normally retails for $30), the FAQs offer no guidance allowing a group health plan to limit its reimbursement to the manufacturer's retail price. Requiring the group health plan to cover the full $100 cost will place a significant strain on an already expensive requirement given, for example, that a group health plan must cover a minimum of 32 tests per month for a family of four participants.

Coverage of Preventive Services

Follow-Up Colonoscopies Without Cost-Sharing

Effective for plan years on or after May 31, 2022 (January 1, 2023 for calendar year plans), the FAQs require that non-grandfathered group health plans cover, without cost-sharing, a colonoscopy conducted after a positive noninvasive stool-based screening test or direct visualization screening test for colorectal cancer for adults ages 45-75. The FAQs note that such follow-up colonoscopies are an integral part of preventive screening, without which the screening would not be complete.

Contraceptive Products and Services Without Cost-Sharing

Pointing to numerous complaints from participants who have been denied contraceptive coverage in violation of the contraceptive mandates under Section 2713 of the Public Health Services Act, the Departments cautioned active investigation of these complaints or other corrective actions. The FAQs remind nonexempt group health plans that they are required to cover all FDA-approved, cleared, or granted contraceptive products that are determined by an individual's medical provider to be medically appropriate to such individual without cost-sharing, whether or not specifically identified in the current FDA Birth Control Guide. The FAQs clarify that this means that a plan may need to cover a newer contraceptive product–such as a mobile app for contraception based on fertility awareness—if it is deemed medically appropriate.

While coverage of preventive care services has always been an area of audit for group health plans, these FAQs heighten awareness for group health plans that the Departments will likely be increasing audit and enforcement activities to ensure compliance with the preventive care services requirements. Group health plan sponsors should take active measures to confirm that their third-party administrators or insurance issuers are complying with these coverage requirements.

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